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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/849,525	08/29/1997	GHITA LANZENDORFER	435-WCG	3976
7590 09/13/2006 Greenblum & Bernstein, P.L.C. 1950 Roland Clarke Place Reston, VA 20191			EXAMINER COTTON, ABIGAIL MANDA	
			ART UNIT 1617	PAPER NUMBER
DATE MAILED: 09/13/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 08/849,525	Applicant(s) LANZENDORFER ET AL.	
	Examiner Abigail M. Cotton	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 June 2006 and 06 July 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 37-56 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 37-56 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>7/6/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This office action is in response to the amendment and remarks submitted on June 2, 2006. Claims 1-36 have been canceled, and claims ~~3~~37-56 have been newly presented and are being examined on the merits herein.

The following rejections have been necessitated by Applicants' presentation of new claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 37-38, 43 and 48-50 are rejected under 35 U.S.C 103(a) as being unpatentable over U.S. Patent No. 5,358,752 to Evans et al, in view of 5,145,781 to Suzuki et al. (of record), and as evidenced by the entry in *Harrisons' Principles of Internal Medicine*, 1994, chapter 55, photosensitivity and other reactions to light, pages 309-313 (of record.)

Evans et al. teaches a skin care composition containing an antioxidant that reduces the accumulation of lipid peroxides and other biological oxidation products in the skin (see abstract, in particular.) Evans et al. teaches that skin issues such as wrinkling and melanoma and other cancers are thought to be accelerated by accumulation of peroxides in skin tissues, and that such peroxides are produced by environmental factors such as exposure to UVB radiation, which is considered to be a primary cause of sunburn and melanoma (see column 1, lines 20-30, in particular.) Evans et al. teaches that it is desirable to provide antioxidants in skin care products for the control of skin tissue itself, and particularly to control peroxide formation in skin exposed to sunlight having a harmful intensity of UVB radiation (see column 1, lines 48-57, in particular.) Evans et al. teaches that antioxidants can be applied to skin to prevent oxidative damage cause by UV radiation (see column 4, lines 22-28, in particular), and the antioxidants may also be applied to skin to control oxidation resulting from burns to the skin and underlying tissues, such as in sun burn formulations (see column 4, lines 29-35 and Example 5, in particular.) Thus, Evans et al. teaches the topical application to skin of a composition comprising an antioxidant to control the oxidative damage of skin damaged by UVB radiation.

Evans et al. does not specifically teach applying to the skin an antioxidant comprising one of the flavonoids, as recited in claim 37. Evans et al. also does not specifically teach applying an antioxidant to the skin of a patient that is in need of

treatment or modulation of the immunosuppression of skin cells induced by UVB radiation, as recited in claim 37.

Suzuki et al. teaches that alpha-glycosyl rutin has properties as an antioxidant and is uv-absorbent, and can be provided in pharmaceuticals and cosmetics (i.e. for topical application) (see abstract, in particular.) Suzuki et al. teaches that the alpha-glycosyl rutin acts as an antioxidant to exhibit activities of removing activated oxygen and suppressing the formation of lipoperoxides (see column 8, lines 15-29, in particular.) Suzuki et al. teaches that the alpha-glycosyl rutin is mainly composed of alpha-glucosyl rutin (see column 2, lines 55-60, in particular), and thus teaches the flavonoid as recited in claim 37.

Accordingly, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the alpha-glucosyl rutin of Suzuki et al. in the skin treatment method of Evans et al, because Evans et al. teaches that antioxidants can be applied to skin to control oxidative damage from UVB radiation, such as in sunburn, whereas Suzuki et al. teaches that alpha-glucosyl rutin has antioxidative effects and can be suitably provided in cosmetic compositions. Thus, one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the alpha-glucosyl rutin in the treatment method of Evans et al, with the expectation of providing a suitable antioxidant effective for reducing controlling oxidative damage caused by exposure to UVB radiation.

Regarding the "effective amount" of the flavonoid, as recited in claim 37, Suzuki et al. teaches that the alpha-glycosyl rutin mainly composed of alpha-glucosyl rutin can be provided in an amount of 0.001 w/w% or more in cosmetics (see column 8, lines 45-57, in particular), which is an amount that overlaps with the ranges recited in the claims, and Evans et al. teaches that an effective amount of an antioxidant added to a product may vary from 1 to 100,000 ppm by weight based on the total weight of the product (see column 4, lines 1-15, in particular.) Furthermore, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of antioxidant provided in the composition, according to the guidance provided by Evans et al. and Suzuki et al, to provide a composition having desired properties, such as desired skin treatment. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Evans et al. and Suzuki et al. do not specifically teach applying an antioxidant to the skin of a patient that is in need of treatment or modulation of the immunosuppression of skin cells induced by UVB radiation, as recited in claim 37.

However, as evidenced by the entry in *Harrison's*, excessive exposure to UVB radiation is implicated in the development of a number of skin disorders, including the

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immunosuppression of skin cells (see page 309, final full paragraph), which is believed to lead to a risk of cancer development in human skin (see page 310, first and second full paragraphs, in particular.) Accordingly, the entry in *Harrison's* teaches that excessive amounts of UVB radiation can lead to immunosuppression of skin cells, and thus it is considered that the population of individuals that has been exposed to excessive UVB radiation, such as those having sunburn, are a population that closely overlaps with and/or is the same as those patients in need of treatment or modulation of the immunosuppression of skin cells induced by the UVB radiation.

Accordingly, it is considered that the skin treatment method of Evans et al. and Suzuki et al, as evidenced by the entry in *Harrison's*, provides treatment or modulation of immunosuppression of skin cells induced by UVB radiation because the method of Evans et al. and Suzuki et al. teaches the treatment of skin, such as sunburned skin, which has been exposed to excessive UVB radiation, and which is thus likely to have immunosuppression of the skin cells.

Regarding the recitation that "immunosuppression of skin cells induced by UVB radiation is treated or modulated," as recited in claim 37, it is noted that as the combined teachings of the references renders the claimed composition and method of using the composition obvious, the property of such a claimed composition and method of use will also be rendered obvious by the prior art teachings, since the properties, namely the treatment or modulation of the immunosuppression, are inseparable from its

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composition. Therefore, if the prior art teaches the composition or renders the composition obvious, then the properties are also taught or rendered obvious by the prior art. In re Spada, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990.) See MPEP 2112.01. The burden is shifted to Applicant to show that the prior art product and method of using the product does not possess or render obvious the same properties as the instantly claimed method of using the product. Accordingly, claim 37 is obvious over the teachings of Evans et al. in view of Suzuki et al. in view of the entry in *Harrison's*.

Regarding claim 38, the references teach a method that treats immunosuppression, as discussed above. Regarding claim 43, Evans et al. teaches that a phenolic diterpene compound can be provided as an antioxidant in the composition (see abstract, in particular.)

Regarding claim 48, Suzuki et al. teaches that rutin can also be provided as an antioxidant in a cosmetic composition (see column 1, lines 45-55, in particular), and thus it is considered that it would be obvious to incorporate rutin as the antioxidant in the method of Evans et al. for the same reasons as described above for alpha-glycosyl rutin.

Regarding claim 49-50, Suzuki et al. teaches that the alpha-glycosyl rutin mainly composed of alpha-glucosyl rutin can be provided in an amount of 0.001 w/w% or more

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in cosmetics (see column 8, lines 45-57, in particular), which is an amount that overlaps with the ranges recited in the claims, and Evans et al. teaches that an effective amount of an antioxidant added to a product may vary from 1 to 100,000 ppm by weight based on the total weight of the product (see column 4, lines 1-15, in particular.) Furthermore, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of antioxidant provided in the composition, according to the guidance provided by Evans et al. and Suzuki et al, to provide a composition having desired properties, such as desired skin treatment. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Claims 39-43, 44-47, 51-53 and 55-56 are rejected under 35 U.S.C 103(a) as being unpatentable over U.S. Patent No. 5,358,752 to Evans et al, in view of 5,145,781 to Suzuki et al, and as evidenced by the entry in *Harrisons' Principles of Internal Medicine*, 1994, chapter 55, photosensitivity and other reactions to light, pages 309-313, as applied to claims 37-38, 43 and 48-50 above, and further in view of U.S. Patent No. 5,023,235 to N'Guyen et al, issued June 11, 1991 (hereinafter N'guyen et al (1).)

Evans et al, Suzuki et al. and *Harrison's* are applied as discussed above, and teach the claimed method comprising applying to skin, which has been immunosuppressed by UVB radiation, a flavonoid such as those recited. Evans et al,

Suzuki et al. and *Harrison's* teach that the application of antioxidants such as the flavonoid provides the skin treatment.

The references do not specifically teach applying a composition that further comprises a cinnamic acid derivative, as recited in claims 39-42, and thus does not teach claims 44-45 depending therefrom or the ratio of flavonoid and cinnamic acid derivatives as in claims 51-52. The references also do not specifically teach providing an antioxidant that is tocopherol or is derivatives, as recited in claims 46-47. The references also do not specifically teach providing the composition in the form of an emulsion, as recited in claim 53.

N'Guyen et al. (1) teaches that caffeic acid and its esters as well as tocopherols are known to have antioxidant activity (see column 1, lines 35-40, in particular), and that the caffeic acid can be suitably incorporated into cosmetic compositions (see column 1, lines 15-20, column 2, lines 53-57 and column 3, lines 24-27, in particular.) Thus, N'Guyen et al. (1) teaches providing an antioxidant that is caffeic acid, the hydroxycinnamic acid derivative as recited in claims 39-42, and also teaches providing another antioxidant, as in claims 44-45, such as tocopherol, as recited in claims 46-47.

Accordingly, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the caffeic acid and/or tocopherol of Nguyen et al. (1) in the skin treatment method of Evans et al, Suzuki et al.

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and *Harrison's*, because Evans et al, Suzuki et al. and *Harrison's* teach that antioxidants can be applied to skin in the method to control oxidative damage from UVB radiation, such as in sunburn, whereas N'Guyen et al. (1) teaches that caffeic acid and tocopherols have antioxidative effects and can be suitably provided in cosmetic compositions. Thus, one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the caffeic acid and/or tocopherols in the treatment method of Evans et al, Suzuki et al. and *Harrison's* with the expectation of providing a suitable antioxidant effective for reducing controlling oxidative damage caused by exposure to UVB radiation. Accordingly, claims 39-42 and 44-47 are obvious over the references.

Regarding claims 51-52, Evans et al. and Suzuki et al. teach suitable amounts for antioxidants such as the flavonoid and caffeic acid in the composition, and N'guyen et al. further teaches suitable amounts of the caffeic acid in a cosmetic composition (see column 3, lines 55-63, in particular.) Furthermore, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount and/or ratios of antioxidants provided in the composition, according to the guidance provided by the references, to provide a composition having desired properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Regarding claim 53, it is noted that Evans et al. teaches that the antioxidants can be applied to the skin in a carrier that is any cosmetically acceptable liquid or semi-solid materials (see column 3, lines 45-50, in particular.) Although Evans et al, Suzuki et al. and *Harrison's* do not specifically teach an emulsion as an example of a cosmetically acceptable carrier material, N'guyen et al. (1) teaches providing water-in-oil emulsions as carriers for cosmetics (see Example I, in particular), and thus teaches that emulsions are known as cosmetically acceptable carriers. Thus, it is considered that one of ordinary skill in the art at the time the invention was made would have been motivated to provide an emulsion, as taught by N'guyen et al. (1), as the carrier for the composition of Evans et al, Suzuki et al. and *Harrison's*, with the expectation of providing a cosmetically acceptable carrier for the composition.

Regarding claim 55, it is noted that Evans et al, Suzuki et al, and *Harrison's* teach the claim method of treating skin by applying a flavonoid as claimed, and also teach that the composition can comprising another antioxidant, such as rutin, as has been discussed for claims 37 and 43 above. Also, N'guyen et al. (1) teaches that caffeic acid has antioxidant properties and can be incorporated into a cosmetic composition, and thus it is considered obvious that it would have been obvious to incorporate the caffeic acid of N'guyen et al. (1) into the method of Evans et al, Suzuki et al, and *Harrison's*, for the reasons as set forth for claims 39-42 above.

Furthermore, Regarding the recitation that "immunosuppression of skin cells induced by UVB radiation is treated," as recited in claim 55, it is noted that as the combined teachings of the references renders the claimed composition and method of using the composition obvious, the property of such a claimed composition and method of use will also be rendered obvious by the prior art teachings, since the properties, namely the treatment or modulation of the immunosuppression, are inseparable from its composition. Therefore, if the prior art teaches the composition or renders the composition obvious, then the properties are also taught or rendered obvious by the prior art. In re Spada, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990.) See MPEP 2112.01. The burden is shifted to Applicant to show that the prior art product and method of using the product does not possess or render obvious the same properties as the instantly claimed method of using the product. Accordingly, claim 55 is obvious over the teachings of Evans et al. in view of Suzuki et al. as evidenced by the entry in *Harrison's*, and further in view of N'Guyen et al. (1)

Regarding claim 56, N'guyen et al. (1) teaches providing caffeic acid, a hydroxycinnamic acid derivative, and tocopherol, as discussed above, and thus the claim is obvious over the references.

Claim 54 is rejected under 35 U.S.C 103(a) as being unpatentable over U.S. Patent No. 5,358,752 to Evans et al, in view of 5,145,781 to Suzuki et al, and as evidenced by the entry in *Harrisons' Principles of Internal Medicine*, 1994, chapter 55,

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photosensitivity and other reactions to light, pages 309-313, as applied to claims 37-38, 43 and 48-50 above, and further in view of U.S. Patent No. 5,114,716 to N'guyen et al, issued May 19, 1992 (hereinafter N'guyen et al. (2))

Evans et al, Suzuki et al. and *Harrison's* are applied as discussed above, and teach the claimed method comprising applying to skin, which has been immunosuppressed by UVB radiation, a flavonoid such as those recited. Evans et al, Suzuki et al. and *Harrison's* teach that the application of antioxidants such as the flavonoid provides the skin treatment. Evans et al. further teaches that the antioxidants can be applied to the skin in a carrier that is any cosmetically acceptable liquid or semi-solid materials (see column 3, lines 45-50, in particular.)

Evans et al, Suzuki et al. and *Harrison's* do not specifically teach a gel as an example of a cosmetically acceptable carrier material, as recited in claim 54.

N'guyen et al. (2) teaches that gels are known as cosmetically acceptable carriers for cosmetics (see Example III, in particular.)

Thus, it is considered that one of ordinary skill in the art at the time the invention was made would find it obvious to provide a gel, as taught by N'guyen et al. (2), as the carrier for the method as taught by Evans et al, Suzuki et al. and *Harrison's*, because Evans et al, Suzuki et al. and *Harrison's* teach that any cosmetically

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acceptable carrier can be provided, and N'guyen et al. (2) teaches that gels are known as cosmetically acceptable carriers. Thus, one of ordinary skill in the art would have been motivated to provide a gel as the carrier for the composition of Evans et al, Suzuki et al. and *Harrison's*, with the expectation of providing a suitable cosmetically acceptable carrier for the composition.

Response to Arguments

Applicant's arguments with respect to the rejections of the claims have been considered but are moot in view of the new grounds of rejection.

Conclusion

No claims are allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The Chapter "The Impact of Plant Flavonoids on Mammalian Biology: Implications for Immunity, Inflammation and Cancer" by Middleton et al, in the book "The Flavonoids: Advances in Research since 1986," 1984 (of record), teaches that flavonoids in general are known to modulate immune and inflammatory cell functions (see Section 15.3, in particular.) U.S. Patent No. 5,340,568 to Piazza et al. teaches that wrinkles caused by exposure to ultraviolet radiation, can be treated with a

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topical composition comprising an antioxidant (see column 1, lines 15-25 and column 13, lines 4-36, in particular.)

Applicant's amendment necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

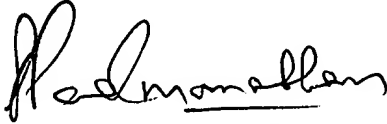
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abigail M. Cotton whose telephone number is (571) 272-8779. The examiner can normally be reached on 9:30-6:00, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AMC



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